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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,960	07/25/2003	Ary S. Chernomorsky	RUBI5873	2271
22430	7590	05/31/2005	EXAMINER	
YOUNG LAW FIRM A PROFESSIONAL CORPORATION 4370 ALPINE ROAD SUITE 106 PORTOLA VALLEY, CA 94028			DAWSON, GLENN K	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



***Election/Restrictions***

Claims 34-39 and 71-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04-22-2005.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 11-15, 18 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Vidal, et al.-5334216.

Vidal discloses a collagen hemostatic plug having portions of different densities which would inherently cause the two portions to have different pore characteristics such as pore density or pore orientation. The plug is made out of collagen, gelatin and PGA material as well as thrombin. The plug's portions are constructed so that the portions have different swelling characteristics upon receipt of body fluids. See col. 2 lines 3-56; col. 4 lines 45-51.

Claims 1-4, 12, 13, 15, 18 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Urbanski-6183496.

Urbanski discloses a collagen hemostatic plug made of collagen filaments. The two sheets that make up the plug have different densities causing different pore characteristics. The plug will therefore have portions which swell differently upon receipt of body fluids. See col. 5 lines 52-63; col. 6 lines 3-20; col. 7 lines 57-61.

Claims 1-4, 12, 13, 15-19, 28-30, 40-42, 50, 51, 53-57, 64-66 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Krajicek-5522840.

Krajicek discloses a swellable collagen plug made out of two facing layers. The two layers have different degrees of cross-linking by the tanning process which causes the two portions to swell differently upon receipt of body fluids. See col. 3 lines 7-38.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 31,32,67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krajicek-'840 in view of Li-6090996.

Krajicek discloses the invention as claimed with the exception of the type of cross-linking. Li discloses that it was known to cross-link collagen matrixes by formaldehyde, glutaraldehyde or a dehydrothermal process. See col. 1 lines 24-30; col. 2 lines 21-31; col. 3 lines 29-64; col. 4 lines 21-29 and 48-60; and col. 5 lines 19-24. It would not have involved an inventive step to have used the cross-linking methods of Li in making the implant of Krajicek, as these methods have been shown to be effective at forming a stable matrix.

Claims 33 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krajicek-'840 in view of Rhee, et al. 5510418.

Krajicek discloses the invention as claimed with the exception of cross-linking the matrix by a combination of both cyanamide and a dehydrothermal process. As both of these methods were known, as taught by Rhee in col. 2 lines 38-45, to have used both of the cross-linking methods of Rhee in making the implant of Krajicek would not have involved an inventive step as these methods have been shown to be individually effective at forming a stable matrix, and using both would have produced a stable matrix as well.

Claims 5,8-11,23,43,46-49 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krajicek-'840 in view of Fulton, et al.-6270464.

Krajicek discloses the implant as claimed with the exception of the additives in the matrix. Fulton discloses the use of the claimed additives. See col. 2 lines 28-55 and col. 3 lines 50-60. It would not have involved an inventive step to have added the contrast agents and the bioactive agents, as these would allow for non-invasive detecting of the position of implantation of the plug and would allow for the clotting of blood and the prevention of infection.

Claims 5-7,10,11,14,23,24,43,44,45,48,49,52,61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krajicek-'840 in view of Sing, et al.-6183497.

Krajicek discloses the invention as claimed with the exception of the additives. Sing discloses the use of radiopaque materials, radioactive materials and thrombin. See col. 2 lines 52-59; col. 3 lines 11-20 and 45-60; and col. 8 lines 24-38. It would not have involved an inventive step to have added the additives of Sing to the plug of Krajicek, as these materials allow for blood clotting, treatment of cancerous cells and non-invasive imaging of the location of the plug in the patient's body.

#### ***Allowable Subject Matter***

Claims 20-22,25-27,58-60 and 63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or fairly suggest the implant of claim 1 including an

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internal reservoir to contain a dye, pigment or therapeutic agent; a third porous portion forming with the first and second portions a predetermined pore density gradient; an implant having portions with differing cross-linking densities; a method of mapping a lymphatic system following a cavity generating procedure, including providing an implant having a collagenous matrix with non-uniform cross-linking density and a dye or pigment which swells non uniformly, implanting it into the cavity, closing the cavity, causing the dye or pigment to be released to propagate through the lymph system and visualizing the pigment in the lymph system.

#### ***Information Disclosure Statement***

The information disclosure statements (IDS) submitted on 08-15-2003, 12-29-2003 and 03-09-2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 703-308-4304. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Glenn K Dawson  
Primary Examiner  
Art Unit 3731

Gkd  
27 May 2005